

REMARKS

This Response is submitted in reply to the final Office Action mailed on January 10, 2006. No fee is due in connection with this Response. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-36 on the account statement.

Claims 1-16 are pending in this application. In the Office Action, Claims 1-16 are rejected under 35 U.S.C. §102. For the reasons set forth below, Applicants respectfully submit that the rejection should be withdrawn.

In the Office Action, Claims 1-16 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,849,335 to Ballevre et al. ("*Ballevre*"). Applicants respectfully disagree with and traverse this rejection for at least the reasons set forth below.

Independent Claims 1-3 recite, in part, a method comprising the step of administering a nutritional composition including a protein source having at least 80% by weight of a component selected from the group consisting of whey protein and a protein mixture which simulates the amino acid profile of whey protein consisting of approximately 80% to about 90% by weight of casein. Applicants submit that the selection of the protein component in Claims 1-3 is either one component or the other and does not include mixtures of the two. In contrast, Applicants respectfully submit that *Ballevre* fails to disclose or suggest every element of the present claims.

Applicants respectfully disagree with the Patent Office's assertion, in regard to the percentages of the whey protein, that the percentages claimed is inherent in the casein of milk which allegedly reads on the limitation of approximately 80-90% by weight of casein and further allegedly overlaps with the disclosed amount of about 10-30% of mixtures of whey and casein because approximately is a relative term. See, Office Action, page 4. For example, the Patent Office has failed to provide any evidence of the percentage of casein in milk or that percentage of milk used as the protein source in *Ballevre*. Moreover, the term "approximately" means near or close in degree and would not encompass a difference of 50% (e.g. 80% of casein in Claims 1-3 minus 30% maximum of whey and casein disclosed in *Ballevre*) as alleged above by the Patent Office.

Balleve fails to disclose or suggest a nutritional composition including a protein source having at least 80% by weight of a component selected from either whey protein OR a mixture which simulates the amino acid profile of whey protein consisting of approximately 80% to about 90% by weight of casein as required by the present claims. Instead, *Balleve* discloses that carob protein comprises about 40% to about 100% by weight of the protein source of its nutritional composition, which results in the protein source in *Balleve* containing a minimum of "about 40%" of the protein source of carob. This means that the theoretical maximum whey or casein content would be about 60% (e.g. $100\% - 40\% = 60\%$) because carob protein comprises the majority of the protein source. This is a difference of 20% from what the present claims require and therefore does not reasonably fall within the "approximate" range. Moreover, the description of *Balleve* in any event teaches away from this by teaching a maximum whey content (or mixture of whey and casein) of 30% of the protein source, which is even further from the claimed ranges. See, *Balleve*, column 4, lines 28-36. As a result, Applicants respectfully submit that *Balleve* fails to disclose or suggest a composition having the claimed ranges of whey protein OR a mixture which simulates the amino acid profile of whey protein.

Further, *Balleve* is entirely directed to the use of a protein source comprising carob protein, which is rich in glutamine. As a result, it teaches away from Applicants' present claims wherein the protein source contains a low concentration of glutamine (e.g. because the protein source comprises at least 80% by weight whey protein). See, *Balleve*, Abstract and column 2, lines 33-42. In fact, *Balleve* is concerned with a glutamine rich nutritional composition used for glutamine supplemented diets. See, *Balleve*, column 2, lines 27-30.

As stated in Applicants' specification, the present invention is based on the surprising discovery that feeding whey protein to individuals in need of glutamine supplementation improves plasma glutamine status more than would be expected having regard to the amount of glutamine present in whey protein. See, specification, page 3, lines 4-11. As is observed from Example 2 of Applicants' specification and known by one having ordinary skill in the art, whey protein contains a lower proportion of glutamine than both casein and soy protein, yet better plasma and muscle glutamine status is obtained by feeding whey protein than by feeding casein and soy proteins. Thus, the present claims are directed to a novel way of increasing glutamine levels in mammals using whey protein or a protein mixture which simulates the amino acid

profile of whey protein and not simply a way of supplementing glutamine with carob protein as in *Balleve*.

In sum, Applicants have discovered the novel way of increasing glutamine levels in mammals by providing nutritional compositions that have relatively low glutamine levels themselves. Applicants have carefully researched the desirability, applicability and levels of protein sources to be effectively used for such increases to occur. Nowhere does *Balleve* recognize or successfully employ the claimed nutritional products comprising a protein source having at least 80% by weight of a whey protein or a protein mixture which simulates the amino acid profile of whey protein to increase glutamine levels in mammals. As a result, *Balleve* fails to disclose or suggest the presently claimed methods.


For the reasons discussed above, Applicants respectfully submit that Claims 1-3 and Claims 4-16 that depend from these claims are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1-16 under 35 U.S.C. §102(b) be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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